3.2 Medical Requirements Overview

TABLE 3.2: MEDICAL REQUIREMENT OVERVIEW

MRID# and Title	MEDB 2.1 Laboratory Testing
Sponsor	Medical Operations
Discipline	N/A
Category	Medical Requirements (MR)
References	ISS Medical Operations Requirements Document (MORD), SSP 50260 MED Volume B Section 2.1, SSP 50667
Purpose/Objectives	To evaluate crewmember medical fitness for flight and for post-flight recovery by analysis of clinical specimens.
Measurement Parameters	Clinical laboratory examination includes blood for hematology, clinical biochemistry; and urine for routine urinalysis
Deliverables	Preflight and postflight Medical Assessment Testing (MAT) reports to the crew surgeon.
Flight Duration	≥30 days
Number of Flights	All flights
Number and Type of Crewmembers Required	All prime and back-up crewmembers for preflight, and prime crewmembers for postflight.
Other Characteristics	Methicillin Resistant Staphylococcus Aureus (MRSA) Screening and Suppression is referenced in MEDB 2.4

3.3 Preflight Training - None

3.4 Preflight Activities

TABLE 3.4: PREFLIGHT ACTIVITIES

<table>
<tr><td>Preflight Activity
Description</td><td colspan="5">Clinical Laboratory Testing will be performed on L-90/30 days and L-20/10 days. The examination will include collection of blood and urine from crewmembers for analyses to enhance the physician’s medical evaluation of crew health prior to flight.

Preflight Clinical Laboratory Testing will include the following:
L-90/30 days:
• Blood (10-hr fast required): Hematology – CBC w/differential, reticulocytes; Chemistry profile – glucose, BUN, creatinine, AST, ALT, GGTP, alkaline phosphatase, total bilirubin, total protein, electrolytes, calcium, magnesium, phosphorus, LDH, uric acid, albumin; Ionized calcium; Thyroid function – free T4, TSH; Iron profile – iron, iron binding capacity, transferrin saturation, ferritin; Special chemistry – C-reactive protein, Serum lipids (total cholesterol, LDL, HDL, Triglycerides);Bone Markers Panel; Mouse IgE Allergen Panel; Archive tube.
• Blood: Serum HCG on females

• Urine: Urinalysis

L-20/10 days (female crewmembers only):

• Urine: urine pregnancy test</td></tr>
<tr><td rowspan="3">Schedule</td><td>Duration</td><td>Schedule</td><td>Flexibility</td><td>Blood Volume</td><td>Personnel Required</td></tr>
<tr><td>Blood Collection - 10 min

Random Urine Collection - 5 min</td><td>L-90/30 days</td><td rowspan="2">Contact lab to assess if schedule accommodations are possible</td><td>30 mL

N/A</td><td>Crewmembers/ Lab Personnel

Self-collected</td></tr>
<tr><td>Urine Collection - 5 min. (females only)</td><td>L-20/10 days</td><td>N/A</td><td>Female Crewmembers/ Lab Personnel</td></tr>
<tr><td>Ground Support Requirements Hardware/Software</td><td colspan="5"><table>
<tr><th>Preflight Hardware:</th><th>Preflight Software:</th><th>Test Location:</th></tr>
<tr><td>Blood Collection supplies & consumables
Urine Collection supplies & consumables
Hematology instrumentation & consumables
Biochemistry instrumentation & consumables
Immunology instrumentation & consumables</td><td>N/A</td><td>U.S. /Russia
U.S. /Russia
U.S. /Russia
U.S.
U.S.</td></tr>
</table></td></tr>
</table>

TABLE 3.4: PREFLIGHT ACTIVITIES (cont'd)

Testing Facilities	**Minimum room dimensions:**	**Number of electrical outlets:**	**Temperature requirements:**	**Special lighting:**
	Two rooms, each with dimensions of 10′ x 10′	Minimum 12 (in U.S. 120V, in Russia 220V & power converter)	Ambient	Sufficient lighting for blood collection & laboratory bench work.
	Hot or cold running water:	**Privacy requirements:**	**Vibration/Acoustic Isolation:**	**Other:**
	Sink with hot and cold water for hand-washing.	Private rooms free from distractions. Access to restroom for urine collection.	N/A	Room 1 (Laboratory): Countertops or tables, cabinets, 4 chairs (minimum), refrigerator/freezer, and centrifuge, in a room designated "Laboratory". Room 2 (Blood Collection Area): Gurney (1), table (1), and chairs (2) in a room designated as "Sample Collection Area". Restroom
Constraints/Special Requirements	• For L-90/30 blood draws, the crewmember is required to fast for 10 hours before blood collection. • Urine collections – Second void of the morning required • Mouse IgE Allergen Panel: L-90/30 and the R+3 testing for Mouse IgE Allergen Panel will be sent to the reference laboratory as a paired sample.			
Launch Delay Requirements	Clinical Laboratory analyses will be repeated at the crew surgeon's discretion if launch is delayed.			
Notes	• Upon completion of analyses, any remaining aliquots of all blood samples are archived frozen at the JSC Clinical Laboratory. • Consumables and Hematology instrumentation will be hand-carried to Russia. Preflight sample collection outside of U.S.: Sample collection and processing occurring in Russia will require analyses of samples for tests that are time critical. • Some analyses will be performed in Russia by JSC Clinical Laboratory personnel using equipment hand-carried from the U.S. • Aliquots of blood and urine samples collected by JSC Clinical Laboratory personnel in Russia will be packed in dry ice and hand-carried to the U.S. to be analyzed at JSC. • The JSC Clinical Laboratory will analyze samples within 24-72 hrs of laboratory receipt of samples from Russia.			
Data Delivery	• All hematology, urinalysis and clinical chemistry data will be entered into the Laboratory Information System within 24-72 hrs after laboratory receives samples; data will reside in the crewmembers Electronic Medical Record. Hard copies of the data will be provided to the Crew Surgeon upon request. • Reports from test samples sent to a reference laboratory will be entered into the Laboratory Information System as the results are received in the Clinical Laboratory and will reside in the crewmembers Electronic Medical Record. Copies of the data will be provided to the Crew Surgeon upon request.			

3.5 **In-Flight Activities –** Blood and urine testing only as clinically indicated, including pre- and post EVA

3.6 Postflight Activities

TABLE 3.6: POSTFLIGHT ACTIVITIES

Postflight Activity

Description

Clinical Laboratory Testing will be performed on R+0/1 (landing day), R+3/7 days, and R+14/30 days. The examination will include collection of blood and urine for analyses to enhance the physician's medical evaluation of postflight crew health.

Postflight Clinical Laboratory Testing will include the following:

R+0/1 days:

- Blood (10-hr fast required): Hematology - CBC w/differential,; Archive tube i-Stat: Na, K, glucose, ionized calcium, pH
- Urine*:* Urinalysis

R+3/7 days: as clinically indicated

- Blood (10-hr fast required): Hematology - CBC w/differential, reticulocytes; Chemistry profile – glucose, BUN, creatinine, AST, ALT, GGT, alkaline phosphatase, total bilirubin, total protein, electrolytes, calcium, magnesium, phosphorus, LDH, uric acid, albumin; Iron profile – iron, TIBC, % transferrin saturation, ferritin; Special chemistry – C-reactive protein; Thyroid profile – TSH, FT4; Bone Markers Panel; IgE Allergen Panel

R+14/30 days:

- Blood (10-hr fast required): Hematology - CBC w/differential, reticulocytes; Chemistry profile – glucose, BUN, creatinine, AST, ALT, GGTP, alkaline phosphatase, total bilirubin, total protein, electrolytes, calcium, magnesium, phosphorus, LDH, uric acid, albumin; Iron profile - iron, TIBC,% transferrin saturation, ferritin; Special chemistry – C-reactive protein; Lipid profile (total cholesterol, LDL, HDL, Triglycerides); HgbAlC; Bone markers Panel
- Urine: urinalysis

Schedule

Duration	Schedule	Flexibility	Blood Volume	Personnel Required
Blood Collection – 10 min Random Urine Collection – 5 min	R+0/1	Contact Lab	10 mL N/A	Crewmembers/ Lab Personnel Self-collected
Blood Collection – 10 min	R+3/7 days	Contact Lab	30 mL	Crewmembers/ Lab Personnel
Blood Collection – 10 min Random Urine Collection – 5 min	R+14/30 days	Contact Lab	20 mL N/A	Crewmembers/ Lab Personnel Self-collected

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Medical Requirements Integration Documents (MRIDs) JSC28913

Table 3.6 Postflight Activities (cont'd)

Ground Support Requirements Hardware/Software	**Postflight Hardware:**		**Postflight Software:**	**Test Location:**
	Blood Collection supplies & consumables Urine Collection supplies & consumables Hematology instrumentation & consumables Biochemistry instrumentation & consumables Immunology instrumentation & consumables		N/A	U.S. /Russia U.S. /Russia U.S. /Russia U.S. U.S.
Postflight Activity Facilities	**Minimum room dimensions:**	**Number of electrical outlets:**	**Temperature requirements:**	**Special lighting:**
	Two rooms, each with dimensions of 10′ x 10′	Minimum 12 (in U.S. 120V, in Russia 220V & power converter)	Ambient	Sufficient lighting for blood collection & laboratory bench work.
	Hot or cold running water:	**Privacy requirements:**	**Other:**	
	Sink with hot and cold water for hand-washing.	Private rooms free from distractions. Access to restroom for urine collection.	<u>Room 1 (Laboratory):</u> Countertops or tables, cabinets, 4 chairs (minimum), refrigerator/freezer, and centrifuge in a room designated "Laboratory". <u>Room 2 (Blood Collection Area):</u> Gurney (1), table (1), and chairs (2) in a room designated "Sample Collection Area". <u>Restroom</u>	
Constraints/Special Requirements	• Urine collections – Second void of the morning required • At R+3/7 days & R+14/30 days crewmember is required to fast 10 hours before blood collection. • Mouse IgE Allergen Panel: L-90/30 and the R+3 testing for Mouse IgE Allergen Panel will be sent to the reference laboratory as a paired sample. • Re-evaluate at 1 year to determine if there is a difference between postflight laboratory results at R+3 days versus R+7 days.			
Notes	• Upon completion of analyses, any remaining aliquots of all blood samples are archived frozen in the JSC Clinical Laboratory. • Consumables and Hematology instrumentation will be hand-carried to Russia. **<u>Postflight sample collection outside of U.S.</u>**: Sample collection and processing occurring in Russia will require analyses of samples for test that are time critical. • Some analyses will be performed in Russia by JSC Clinical Laboratory personnel on hand-carried equipment from the U.S. • Aliquots of blood and urine samples collected by JSC Clinical Laboratory personnel in Russia will be packed in dry ice and hand-carried to the U.S. to be analyzed at JSC. • The JSC Clinical Laboratory will analyze samples within 24-72 hrs of laboratory receipt of samples from Russia.			

Data Delivery	• All hematology, urinalysis and clinical chemistry data will be entered into the Laboratory Information System within 24-72 hrs after laboratory receives samples; data will reside in the crewmembers Electronic Medical Record. Hard copies of the data will be provided to the Crew Surgeon upon request. • Reports from test samples sent to a reference laboratory will be entered into the Laboratory Information System as the results are received in the Clinical Laboratory and will reside in the crewmembers Electronic Medical Record. Copies of the data will be provided to the Crew Surgeon upon request.

3.7 Summary Schedule

TABLE 3.7: SUMMARY SCHEDULE

ACTIVITY	DURATION OF ACTIVITY	SCHEDULE	FLEXIBILITY	BLOOD VOLUME	PERSONNEL REQUIRED	CONSTRAINTS
Preflight Training – N/A						
Preflight Activity						
Blood Collection	10 min	L-90/30 days	Contact Lab	30 mL	Crewmembers/ Lab Personnel	Fasting 10 hrs required
Random Urine Collection	5 min			N/A	Crewmembers (self-collected)	Second void of the morning required
Urine Collection	5 min (females only)	L-20/10 days	Contact Lab	N/A	Female crewmembers/Lab Personnel	
In-flight –Blood and urine testing only as clinically indicated, including pre- and post EVA						
Postflight Activity						
Blood Collection	10 min	R+0/1	Contact Lab	10 mL	Crewmembers/ Lab Personnel)	Fasting 10 hrs required
Random Urine Collection	5 min			N/A	Crewmembers (self-collected	Second void of the next morning required
Blood Collection	10 min	R+3/7 days	Contact Lab	30 mL	Crewmembers/ Lab Personnel	Fasting 10 hrs required
Blood Collection	10 min	R+14/30 days	Contact Lab	20 mL	Crewmembers/ Lab Personnel	Fasting 10 hrs required
Random Urine Collection	5 min			N/A	Crewmembers (self-collected)	Second void of the morning required